# This Page Is Inserted by IFW Operations and is not a part of the Official Record

# **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

# IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

Thomas J. Schall et al. Application No.: 09/919,224

Page 5

# IN THE CLAIMS:

# Please amend the following claims as indicated without prejudice or disclaimer:

21. (Once amended) A therapeutic or prophylactic method for treating an immune disorder, comprising:

administering to a patient suffering from or susceptible to the immune disorder a pharmaceutically acceptable dose of rhesus CMV IL-10.

- 22. (Once amended) The method of claim 21, wherein the rhesus CMV IL-10 is a component of a pharmaceutical composition further comprising a pharmaceutically acceptable carrier.
- 23. (Once amended) The method of claim 22, wherein the pharmaceutical composition is sterile, substantially isotonic and prepared under GMP conditions.
- 24. (Once amended) The method of claim 21, wherein the immune disorder is selected from the group consisting of graft-versus-host disease, an autoimmune disease, an inflammatory response, a pathologic delayed type hypersensitivity response, endotoxin-induced toxic shock, granulomatis disease, psoriasis, uveitis, systemic lupus erythematous, multiple sclerosis and contact-dermatitis.
- 25. (Once amended) The method of claim 50, further comprising monitoring proliferation of lymphocytes in the patient to detect a reduction in the level of lymphocyte proliferation responsive to the administering step.
- 26. (Once amended) The method of claim 21, further comprising monitoring a symptom of the patient to detect amelioration of the symptom responsive to the administering step.
- 27. (Once amended) The method of claim 21, wherein the patient is suffering from the disorder and the method is a therapeutic treatment method.

pit

Thomas J. Schall et al. Application No.: 09/919,224 Page 6

b m

- 28. (Once amended) The method of claim 21, wherein the patient is susceptible to the disorder and the method is a prophylactic treatment method.
- 31. (Once amended) The method of claim 30, wherein IFN- $\alpha$  levels of the patient are detectably decreased responsive to the administering of rhesus CMV IL-10.
- 32. (Once amended) The method of claim 21, wherein the immune disorder is a chronic inflammatory disease.
- 33. (Once amended) The method of claim 32, wherein the chronic inflammatory disease is selected from the group consisting of rheumatoid arthritis, inflammatory bowel disease, Crohn's disease, ulcerative colitis, Graves' disease, Hashimoto's thyroiditis, systemic lupus erythematosus, multiple sclerosis, scleroderma, and insulin-dependent diabetes mellitus.
- 34. (Once amended) The method of claim 21, wherein the immune disorder is an allergic response.
- 35. (Once amended) The method of claim 34, wherein the immune disorder is asthma.
- 36. (Once amended) The method of claim 21, wherein the patient is suffering from a type TH1 immune response to a transplanted graft.

A'X

leukemia.

38. (Once amended) The method of claim 25, wherein the immune disorder is



44. (Once amended) A therapeutic or prophylactic method for treating an inflammatory response, comprising administering to a patient suffering from or susceptible to the inflammatory response a pharmaceutically acceptable dose of rhesus CMV IL-10.

Thomas J. Schall et al. Application No.: 09/919,224

Page 7

- 45. (Once amended) The method of claim 44, further comprising monitoring proliferation of leukocytes in the patient to detect a reduction in the level of leukocyte proliferation responsive to the administering step.
- 46. (Once amended) The method of claim 44, further comprising monitoring a symptom of the patient to detect amelioration of the symptom responsive to the administering step.
- 47. (Once amended) The method of claim 44, wherein the patient is suffering from the disorder and the method is a therapeutic method.
- 48. (Once amended) The method of claim 44, wherein the inflammatory response is a chronic inflammatory disease.
- 49. (Once amended) The method of claim 48, wherein the chronic inflammatory disease is selected from the group consisting of rheumatoid arthritis, Crohn's disease, ulcerative colitis, Graves' disease, Hashimoto's thyroiditis and insulin-dependent diabetes mellitus.

## Please add the following new claims:

- 50. (New) The method of claim 21, wherein the patient is a human.
- 51. (New) The method of claim 21, wherein the pharmaceutically acceptable dose is administered as a single dose.
- 52. (New) The method of claim 21, wherein the pharmaceutically acceptable dose is administered as part of a multi-dose regime.
- 53. (New) The method of claim 50, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit proliferation of leukocytes in the human patient.

Capy

Thomas J. Schall et al. Application No.: 09/919,224

Page 8

- 54. (New) The method of claim 50, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit proliferation of peripheral blood mononuclear cells in the peripheral blood of the human patient.
- 55. (New) The method of claim 50, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit cytokine production in the human patient.
- 56. (New) The method of claim 44, wherein the patient is susceptible to the inflammatory response and the method is a prophylactic treatment method.
  - 57. (New) The method of claim 44, wherein the patient is a human.
- 58. (New) The method of claim 44, wherein the pharmaceutically acceptable dose is administered as a single dose.
- 59. (New) The method of claim 44, wherein the pharmaceutically acceptable dose is administered as part of a multi-dose regime.
- 60. (New) The method of claim 57, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit proliferation of peripheral blood mononuclear cells in the peripheral blood of the human patient.
- 61. (New) The method of claim 57, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit cytokine production in the human patient.

## RESPONSE TO RESTRICTION REQUIREMENT

In response to the Restriction Requirement, Applicants elect to prosecute without traverse the claims of Group V, specifically claims 21-38 and 44-49 involving administration of rhesus CMV IL-10 to treat certain disorders. New claims 50-61 fall within this elected group.

A LAND

Thomas J. Schall et al. Application No.: 09/919,224

Page 13

### Murine Model for Graft Verses Host Graft - Versus-Host Disease

### IN THE CLAIMS:

Claims 21-28, 31-36, 38 and 44-49 have been amended as follows without prejudice or disclaimer:

21. (Once amended) A <u>therapeutic or prophylactic</u> method of preventing or <u>for</u> treating an immune disorder-in a patient, comprising:

administering rhesus CMV IL-10 or human CMV IL-10 to a patient suffering from or susceptible to the immune disorder in a dosage sufficient to inhibit proliferation of lymphocytes in the patient, and thereby prevent or treat the disorder a pharmaceutically acceptable dose of rhesus CMV IL-10.

- 22. (Once amended) The method of claim 21, wherein the rhesus CMV IL-10 or human CMV IL-10 is a component of a pharmaceutical composition further comprising a pharmaceutically acceptable carrier.
- 23. (Once amended) The method of claim 21 22, wherein the pharmaceutical composition is sterile, substantially isotonic and prepared under GMP conditions.
- 24. (Once amended) The method of claim 21, wherein the patient is suffering from or susceptible to an immune disorder is selected from the group consisting of graft versus host graft-versus-host disease, an autoimmune disease, an inflammatory response, a pathologic delayed type hypersensitivity response, endotoxin-induced toxic shock, granulomatis disease, psoriasis, uveitis, systemic lupus erythematous, multiple sclerosis and contact-dermatitis.
- 25. (Once amended) The method of claim 21 50, further comprising monitoring proliferation of the lymphocytes in the patient to detect a reduction in the level of lymphocyte proliferation responsive to the administering step.

Thomas J. Schall et al. Application No.: 09/919,224

Page 14

26. (Once amended) The method of claim 21, further comprising monitoring a symptom of the patient, patient to detect amelioration or prevention of the symptom responsive to the administering step.

- 27. (Once amended) The method of claim 21, wherein the patient is suffering from the disorder and the method is a therapeutic treatment method.
- 28. (Once amended) The method of claim 21, wherein the patient is susceptible to the disorder and the method is a prophylactic treatment method.
- 31. (Once amended) The method of claim 30, wherein the IFN- $\alpha$  levels of the patient are detectably decreased responsive to the administering of rhesus or human-CMV IL-10.
- 32. (Once amended) The method of claim 21, wherein the inflammatory immune disorder is a chronic inflammatory response disease.
- 33. (Once amended) The method of claim 32 32, wherein the chronic inflammatory disease is selected from the group consisting of rheumatoid arthritis, inflammatory bowel disease, Crohn's disease, ulcerative colitis, Graves' disease, Hashimoto's thyroiditis, systemic lupus erythematosus, multiple sclerosis, scleroderma, and insulin-dependent diabetes mellitus.
- 34. (Once amended) The method of claim 21, wherein the inflammatory immune disorder is an allergic response.
- 35. (Once amended) The method of claim 34, wherein the inflammatory immune disorder is asthma.
- 36. (Once amended) The method of claim 21, wherein the patient is suffering from a type TH1 immune response to a transplanted graft.
- 38. (Once amended) The method of claim 25 25, wherein the immune disorder is leukemia.

Thomas J. Schall et al. Application No.: 09/919,224

Page 15

44. (Once amended) A therapeutic or prophylactic method of preventing or for treating the symptoms of an inflammatory response, comprising administering rhesus CMV IL-10 or human CMV IL-10 to the to a patient suffering from or susceptible to an the inflammatory response in a dosage sufficient to ameliorate at least some of the symptoms of the inflammatory condition a pharmaceutically acceptable dose of rhesus CMV IL-10.

- 45. (Once amended) The method of claim 44, further comprising monitoring proliferation of the lymphocytes leukocytes in the patient to detect a reduction in the level of leukocyte proliferation responsive to the administering step.
- 46. (Once amended) The method of claim 44, further comprising monitoring a symptom of the patient, patient to detect amelioration or prevention of the symptom responsive to the administering step.
- 47. (Once amended) The method of claim 44, wherein the patient is suffering from the disorder and the method is a therapeutic method.
- 48. (Once amended) The method of claim 44 <u>44</u>, wherein the inflammatory response is a chronic inflammatory response disease.
- 49. (Once amended) The method of claim 48 48, wherein the chronic inflammatory disease is selected from the group consisting of rheumatoid arthritis, Crohn's disease, ulcerative colitis, Graves' disease, Hashimoto's thyroiditis and insulin-dependent diabetes mellitus.

New claims 50-61 have been added follows:

- 50. (New) The method of claim 21, wherein the patient is a human.
- 51. (New) The method of claim 21, wherein the pharmaceutically acceptable dose is administered as a single dose.

Thomas J. Schall et al. Application No.: 09/919,224

Page 16

- 52. (New) The method of claim 21, wherein the pharmaceutically acceptable dose is administered as part of a multi-dose regime.
- 53. (New) The method of claim 50, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit proliferation of leukocytes in the human patient.
- 54. (New) The method of claim 50, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit proliferation of peripheral blood mononuclear cells in the peripheral blood of the human patient.
- 55. (New) The method of claim 50, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit cytokine production in the human patient.
- 56. (New) The method of claim 44, wherein the patient is susceptible to the inflammatory response and the method is a prophylactic treatment method.
  - 57. (New) The method of claim 44, wherein the patient is a human.
- 58. (New) The method of claim 44, wherein the pharmaceutically acceptable dose is administered as a single dose.
- 59. (New) The method of claim 44, wherein the pharmaceutically acceptable dose is administered as part of a multi-dose regime.
- 60. (New) The method of claim 57, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit proliferation of peripheral blood mononuclear cells in the peripheral blood of the human patient.
- 61. (New) The method of claim 57, wherein rhesus CMV IL-10 is administered in an amount sufficient to inhibit cytokine production in the human patient.